REMARKS

In response to the Office Action of August 19, 2008, the present application has been carefully reviewed and amended. Entry of the present amendment and reconsideration of the application are respectfully requested.

Claim Objections

Claims 1-11, and specifically Claims 1, 8 and 9, are objected to various reasons as set forth on Page 2, paragraph 1 of the Office Action mailed August 19, 2008.

Each of these claims[1] has been amended to overcome the objections.

Claim Rejection under 35 USC §112

Claim 3 is rejected under 35 USC §112 second paragraph.

Claim 3 has been cancelled, and thus this rejection is believed overcome.

Claim Rejection under 35 USC §102

Claims 8-18 stand rejected under 35 USC §102 as being anticipated by Krivitski (US Patent 5,453,576) [Paper 20080812, page 3]

[1] Claim 3 has been cancelled.

As cited by the Examiner, the calibration of Krivitski '576 is:

> Another way to calibrate the perivascular sensors or the clamp-on tube sensors of FIGS. **10** and **11** is to make a calibration injection of a known indicator material directly prior to the location of the sound velocity sensor while simultaneously measuring the blood flow through the tube/vessel. A calibration injection into the arterial line, for example by way of arterial inlet ports **230** or **232** in the systems of FIGS. **10** and **11**, respectively, will change the measured sound velocity in the arterial sensors **112** or **180** as follows:
>
> $$\Delta C(t)=\Delta C_b(t)*l_b/(l_t+l_b) \quad \text{(Eq. 12)}$$
>
> or
>
> $$S_{A.cal.isot.sound}=S_{A.b.cal.isot.sound.}*l_b/(l_t+l_b) \quad \text{(Eq. 13)}$$
>
> where $S_{A.cal.isot.sound.}$ is the measured sound velocity dilution area generated by blood sound velocity dilution changes ($S_{A.b.cal.isot.sound}$). From equations 6 and 13 the average flow through the tube/vessel during the time when the indicator passes is expressed as follows:
>
> $$Q_{A.cal.}=\frac{(A_1P+2A_2P_2)\,V_{A.cal.isot.}*l_b}{S_{A.cal.isot.sound}\,(l_t+l_b)} \quad \text{(Eq. 14)}$$
>
> where $Q_{A.cal.}$ is the average flow through the tube/vessel and $V_{A.cal.isot.}$ is the volume of the calibrating injection. (Col. 11)

That is, Krivitski '576 employs a calibration injection into the arterial line and the measurement of sound velocity in arterial sensors (based on l_t and l_b, where l_t is the equivalent path length of ultrasound in the tube/vessel and l_b is the equivalent path length through the blood). [Krivitski '576, Col. 10, lines 7-10]

Claims 8-11

Claims 8-11 have been amended to recite in part "determining a calibration coefficient of the blood property sensor corresponding to the

measured property of the diluted blood and an ultrafiltration rate of a dialyzer in the extracorporeal portion."

There is no disclosure in Krivitski '576 of determining a calibration coefficient of the blood property sensor in the extracorporeal portion corresponding to the measured property of the diluted blood and an ultrafiltration rate of a dialyzer in the extracorporeal portion.

As at least this limitation is absent from Krivitski '576, the outstanding rejection of Claims 8-11 has been overcome.

Claims 12-14

Claims 12-14 have been amended to recite in part "means for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood and one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal portion."

Krivitski '576 employs a calibration injection into the arterial line and the measurement of sound velocity in an arterial sensor (based on l_t and l_b, where l_t is the equivalent path length of ultrasound in the tube/vessel and l_b is the equivalent path length through the blood). [Krivitski '576, Col. 10, lines 7-10].

Therefore, as the presently recited "change in the ultrafiltration rate of a dialysis system in the extracorporeal portion" is not disclosed in Krivitski '576, Claims 12-14 are in condition for allowance.

Claim 15

Claim 15 has been amended to recite in part "means connected to the blood property sensor for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood in the extracorporeal portion and one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal portion."

Krivitski '576 does not disclose the determination of a calibration coefficient corresponding to one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal portion. Therefore, Claim 15 is in condition for allowance.

Claim 16

Claim 16 has been amended to recite in part "(a) changing an ultrafiltration rate in a dialyzer in the extracorporeal blood circuit to induce introducing a known a change to a predetermined blood property; (b) measuring a corresponding change in the blood property at a blood property sensor in the extracorporeal blood circuit; and (c) determining a calibration coefficient of the blood property sensor corresponding to the measured change."

Krivitski '576 does not disclose changing an ultrafiltration rate in a dialyzer and determining a calibration coefficient corresponding to a measured change. Therefore, Claim 16 is in condition for allowance.

Claim 17

Claim 17 has been amended to recite in part "determining a calibration coefficient of the blood property sensor corresponding to the measured change and an ultrafiltration rate of a dialyzer in the extracorporeal blood circuit."

The use of a calibration injection [Krivitski '576, Col. 11, line 15] does not provide for the presently recited determination corresponding to an ultrafiltration rate of dialyzer in the extracorporeal blood circuit. Therefore, Claim 17 is in condition for allowance.

Claim 18

As amended, Claim 18 recites in part "determining the calibration coefficient of the blood property sensor corresponding to the measured blood property and one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal blood circuit."

The use of a calibration injection [Krivitski '576, Col. 11, line 15] does not provide for the presently recited determination corresponding to one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal blood circuit. Therefore, Claim 18 is in condition for allowance.

Claim Rejections under 35 USC §103

Claims 1-7 stand rejected under 35 USC §103 as being unpatentable over Krivitski (US Patent 5,453,576) [Paper 20080812, page 3]

Claims 1, 2 and 4-7 have been amended to recite in part "changing an ultrafiltration rate of the dialysis system to induce a change in a blood property in the filtered blood passing a dilution indicator past the blood property sensor in the venous tubing portion; (c) determining at least one property of the filtered blood passing a blood property sensor in the venous tubing portion; and (d) determining a calibration coefficient of the blood property sensor corresponding to the determined blood property of the filtered blood.

Krivitski '576 does not disclose changing an ultrafiltration rate in the dialysis system to change a blood property, or (as the Examiner states) that the sensors in the venous portion can be calibrated in the same manner as the sensors in the arterial portion.

With respect to the equivalence of the arterial and the venous sensors, applicant respectfully submits there is no reasonable expectation that the same calibration technique of Krivitski '576 would apply in the venous portion. That is, the dialysis system of Claims 1, 2 and 4-7 changes the blood to filtered blood, thus the filtered blood has different characteristics than the (unfiltered) blood. There is no reason to expect that filtered blood would provide a basis for determining a calibration coefficient in a blood property sensor in the venous tubing portion (downstream of the dialysis system). In fact, the filtered blood, being different from the blood in the arterial line suggests that the blood property sensor in the venous tubing portion cannot be calibrated as a blood property sensor in the arterial tubing portion.

Further, Krivitski '576 does not disclose that the ultrafiltration rate of the dialysis system can be changed to induce a change in a blood parameter from which the calibration coefficient of the blood property sensor in the venous tubing portion can be determined.

The absence of at least these two limitations overcomes the outstanding rejection of Claims 1, 2 and 4-7 under 35 USC §103.

Therefore, applicant respectfully submits all the pending claims, Claims 1, 2 and 4-18 are in condition for allowance, and such action is earnestly solicited. If, however, the Examiner believes that any further issues remain, the Examiner is cordially invited to call the undersigned so that any such matters can be promptly resolved.

Please grant any extensions of time required to enter this response and charge any required fees to our deposit account 03-3875.

Respectfully submitted,

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